MAY - 4 2012

Cordis®
a Johnson & Johnson company

510(k) Summary

Submitter: Cordis Corporation, a Johnson & Johnson company
430 Route 22 East
Bridgewater, NJ 08807

Contact Person: Donna Marshall
Manager, Regulatory Affairs
Ph: (908) 541-4781
Fax: (908) 541-4559
e-mail: dmarsha2@its.jnj.com

Date Prepared: May 3, 2012

Device Trade Name: Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter

Device Common Name: Peripheral Transluminal Angioplasty Balloon Catheter

Class: II

Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Product Code: LIT

Predicate Devices:

Device	Company	Product Code	510(k) Number	Predicate for: (if multiple predicates)
Powerflex™ Extreme Powerflex™ P3 & OPTA™ PRO PTA Catheters	Cordis Corporation	LIT	K032737	Design, Materials, Construction, Characteristics
Aviator Plus PTA Balloon Dilatation Catheter	Cordis Corporation	LIT	K071189	Intended Use
Savvy Long and Sleek PTA Catheters	Clearstream Technologies, Ltd.	LIT	K072947	Dimensions – longer lengths (120 x 220 mm)

Traditional 510(k)
Cordis Powerflex™ Pro PTA Catheter

Device Description:

The Powerflex™ Pro Percutaneous Transluminal Angioplasty (PTA) catheter is a catheter with a distal inflatable balloon. The Powerflex™ Pro PTA Catheter is designed for use with a 0.035" guide wire and a catheter sheath introducer and is available in a variety of diameters and lengths. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses.

Indications for Use:

The Powerflex™ Pro Percutaneous Transluminal Angioplasty (PTA) catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Summary of Performance Testing:

The safety and effectiveness of the Powerflex™ Pro PTA Catheter and the substantial equivalence to the predicate devices have been demonstrated via data collected in non-clinical design verification and validation tests and analyses as well as the post-market surveillance data analyses of the predicate devices. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. All materials used in the proposed device are similar to the predicate devices and meet the requirements of ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process.

The following in-vitro performance tests were completed for the Powerflex™ Pro PTA Catheter:

Marker Band Spacing	Balloon Working Length
Balloon Diameter (Nominal, RBP)	Balloon Burst
System Burst (Inflation Lumen)	Marker Band Placement
System Burst (Guide wire Lumen)	Proximal Pull Strength
Hub to Shaft Pull Strength	Tip to Balloon/Inner Body Pull Strength
CSI Insertion	CSI Withdrawal Force
Kink Diameter Catheter Shaft	Guide Wire Compatibility
Inflation/Deflation Time	Useable Catheter Length
Multiple Inflation (System Fatigue)	Rated Burst Pressure
Torque Testing	PreConditioning Tensile Testing
Particle Free	Cytotoxicity
Hemolysis	Physicochemical Aqueous Extraction

Summary of Substantial Equivalence Comparison:

Comparison of the new and the following predicate devices: Cordis Corp. Opta Pro/Powerflex™ P3 PTA Catheter and ClearStream Technologies, Savvy Long (dimensions only) PTA Catheter show that technological characteristics such as materials, components, biocompatibility, performance properties, dimensions (size range), method of delivery, fundamental technology (operating principle), packaging configuration and packaging materials, labeling, manufacturing and sterilization processes featured with the Powerflex Pro PTA Catheter are substantially equivalent to those featured with the currently marketed Cordis Opta Pro/Powerflex P3 PTA Catheter and ClearStream Technologies, Savvy Long (dimensions) PTA Catheter. The intended use of the new and the above predicate devices are identical with the exception of the additional indication for post dilatation of balloon-expandable and self expanding stents in the peripheral vasculature of the subject device; Cordis Corp., Aviator Plus PTA Catheter is the predicate in regards to the post dilatation indication.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing, the Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Cordis Powerflex™ P3 and Opta™ Pro Percutaneous Transluminal Angioplasty Catheters (K032737), Aviator Plus PTA Balloon Dilatation Catheter (K071189) and ClearStream Savvy Long PTA Catheter (K072947).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 4 2012

Cordis Corp.
% Donna Marshall
430 Route 22 East
Bridgewater, NJ 08807

Re: K112797
Trade/Device Name: Powerflex Pro PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 9, 2012
Received: April 10, 2012

Dear Ms. Marshall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Traditional 510(k)
Cordis Powerflex™ Pro PTA Catheter

Indications for Use Statement

510(k) Number (if known): K112797

Device Name:

Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter

Indications for Use:

The Powerflex™ Pro PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Prescription Use __X__ OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112797